

Notice of Allowability

Application No.

09/873,751

Examiner

Traviss C. McIntosh

Applicant(s)

PHILLIPS ET AL.

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to amendment filed 6/24/05.
2. ☒ The allowed claim(s) is/are 1-15.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

JAMES O. WILSON

SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Bill Winter on August 19, 2005.

The application has been amended as follows:

Claim 1 (currently amended): A method for providing a zinc-containing aqueous solution with improved palatability for oral rehydration therapy to a patient in need thereof comprising administering to said patient said aqueous solution comprising:

- a. from about 0.3 mEq to about 95 mEq of zinc per liter;
- b. from about 10 mEq to about 40 mEq of citrate per liter;
- c. from about 30 mEq to about 95 mEq of sodium per liter;
- d. from about 10 mEq to about 30 mEq of potassium per liter; and
- e. a carbohydrate,

wherein the carbohydrate is maintained within the composition at less than about 3% w/w.

Claim 9 (currently amended): The method according to claim 1 in which said zinc is present in the quantity of from about 0.6 mEq/L to about 5 mEq/L.

Art Unit: 1623

Claim 10 (currently amended): The method according to claim 1 in which said zinc is present in the quantity of from about 0.6 mEq/L to about 1.2 mEq/L.

Claim 11 (currently amended): The method according to claim 1 in which said zinc is selected from the group consisting of zinc gluconate, zinc chloride, zinc sulfate, zinc citrate, zinc carbonate, zinc hydroxide, zinc lactate, zinc acetate, zinc fluoride, zinc bromide, and zinc sulfonate.

Claim 14 (currently amended): The method according to claim 1 in which said citrate is present in the quantity of from about 20 mEq/L to about 40 mEq/L.

Claim 15 (currently amended): The method according to claim 1 in which the citrate is selected from the group consisting of potassium citrate, sodium citrate, and citric acid.

Claim 23 is canceled.

The following is an examiner's statement of reasons for allowance: the prior art is not seen to teach or fairly suggest the use of zinc in oral rehydration solutions as the art teaches that zinc inhibits the intestinal absorption of glucose, and since oral rehydration therapy is based on active transport, it thus would be thought to actually diminish the net absorption of sodium and water, thus diminishing the amount of rehydration (see Darmon et al., Journal of Gastro-

Art Unit: 1623

enterology and Nutrition, vol. 25, pp. 363-5). Moreover, zinc is known to have a very metallic and thus unpleasant taste (see Marshal et al., Canadian Family Physician, vol. 44, pp. 1037-42). As such, there is not seen to be any motivation to include zinc into an oral rehydration solution as it would be thought to negatively affect the therapeutic effects of the solution.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

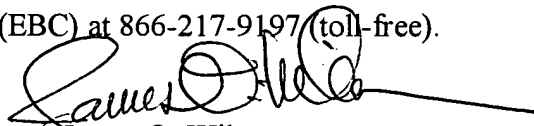
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C. McIntosh whose telephone number is 571-272-0657. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1623

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Traviss C. McIntosh III
August 20, 2005



James O. Wilson
Supervisory Patent Examiner
Art Unit 1623